



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 26 1997

Ms. Benita Bourque, RAC  
Director of Regulatory Affairs  
GAMBRO Healthcare  
1185 Oak Street  
Lakewood, Colorado 80215

Re: K970253  
Centrysystem® 3 plus™ Dialysis Control Unit  
Dated: June 27, 1997  
Received: June 30, 1997  
Regulatory class: III  
21 CFR §876.5860/Product code: 78 KDI

Dear Ms. Bourque:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k)Number: K970253

Device Name: Centrysystem® 3 +plus™ Dialysis Control Unit

Indications For Use:

The Centrysystem® 3 +plus™ Dialysis Control Unit is indicated for patients in acute or chronic renal failure and when hemodialysis is prescribed by the physician. **Both high flux and low flux dialyzers may be used with the Centrysystem® 3 +plus™.** The modifications to the Centrysystem® 3 do not significantly affect the intended uses previously claimed for this device. This device is a totally self contained machine that provides the necessary control functions for hemodialysis therapy, including:

- automatically primes the extracorporeal blood circuit (dialyzer and blood tubing set);
- prepares dialysate;
- monitors machine subsystems for proper performance and unsafe conditions;
- pumps blood, dialysate and anticoagulant at predetermined rates;
- controls fluid removal from the patient; and
- automatically cleans, disinfects and rinses dialysate flow path.

The Centrysystem Cartridge Blood Tubing Set is intended to be used and an extracorporeal circuit accessory to the Centrysystem® 3 +plus™ Dialysis Control Unit described above.

Dolan R. Nathan  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K970253

Prescription Use ✓  
(Per 21 CFR 801.109)

Over-the-Counter Use \_\_\_\_\_

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